Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the drug classes scheduled for review at the September 18, 2003, meeting of the Pharmacy and Therapeutics Advisory Committee and options that were submitted for review.

Drug Class	Options for Consideration
Aloxi (Palonosetron**)**	1. Palonosetron (Aloxi) is Equivalent. (The drug is therapeutically equivalent in both safety and efficacy to the other members of this drug class). 2. Place a quantity limit of 4 vials per month consistent with the restrictions on the other 5-HT_3 antagonists, with larger quantities requiring a prior authorization. 3. Any new 5-HT_3 antagonists (new chemical entity) will be subject to a quantity limit sufficient for therapy of 4 chemotherapy cycles at the usual dose until reviewed by the P&T Committee.
Xolair (Olamizumab)	1. Omalizumab is a Novel agent. (The drug is therapeutically equivalent in both safety and efficacy as compared to other available products for the treatment of asthma, but represents a new therapeutic option, which expands the treatment modality). 2. Require PA for omalizumab with approval for patients who meet the following criteria, which defines the group of patients with moderate to severe asthma and risk factors for significant asthma exacerbation episodes: a. Age ≥ 12 years. b. Non-smoker. c. Positive skin test to perennial aeroallergen. d. IgE baseline level ≥ 30 IU/ml. e. FEV1 < 80%. f. Failure of inhaled corticosteroid in combination with a second controller agent, or contraindication. g. Significant asthma exacerbation episodes as evidenced by at least one of the following: • Systemic corticosteroid treatment (oral or injection) in the past year for treatment of an asthma exacerbation. • ER or hospitalization in the past year related to asthma exacerbation. • Intubation in the past year related to asthma exacerbation.
Proton Pump Inhibitor Therapeutic Class Review	1. All of the proton pump inhibitors are Equivalent. 2. Adopt the most cost-effective PPI as the preferred PPI and require prior-authorization for all other PPI's. Based on current utilization patterns and the average wholesale price (AWP) of the available drugs in this class, the most cost effective PPI's is omeprazole magnesium (Prilosec OTC).

	3. Should the preferred PPI chosen be omeprazole magnesium OTC, select a second preferred PPI from among the prescription products that recipients must utilize before the other PPI's, unless otherwise medically contraindicated. Based on current utilization patterns and the AWP of the available prescription PPI's, the most cost effective product is Protonix. 4. Maintain the current 12-week duration of therapy limit on the PPI's with a required step-down to a preferred H2 receptor antagonist after 12-weeks of PPI therapy, unless otherwise medically contraindicated. 5. Place a PA requirement on any new PPI's (new chemical entity) until reviewed by the P&T Committee.

The following terms will be utilized within the therapeutic monograph to classify medications during Drug Class Reviews. By using these terms, the reviewer will be able to easily identify any clinical differences between the medications within the class being reviewed.

Superior - Following evidence-based review, it is determined that the drug provides a therapeutic advantage, in terms of safety and/or efficacy, over other available products within the same treatment modality.

Novel - Following evidence-based review, the drug is therapeutically equivalent in both safety and efficacy, but represents a new therapeutic option, which expands the treatment modality.

Equivalent - Following evidence-based review, it is determined that the drug is therapeutically equivalent in both safety and efficacy to other available products within the same treatment modality.

Not Essential - Following evidence-based review, it is determined that the drug has no therapeutic advantage, due to either reduced safety or efficacy, over other available products within the same treatment modality.